March 3, 2003

Mr Stuart Shapiro
Desk Officer for the Food and Drug Administration
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th St, NW Room 10235
Washington DC 20503

Re: **Docket No 02N-0276**
Comments to Proposed Facility Registration of Food Facilities Rule

Dear Mr Shapiro:

This letter represents the comments of Northland Cranberries, Inc. ("Northland") relating to economics and information collection in response to the proposed rules for the Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Northland is a vertically integrated grower, handler, processor and marketer of cranberries and value-added cranberry products. Northland sells it own brand of 100% juice cranberry blends and fresh cranberries, as well as *Seneca* brand juice products, through retail supermarkets and other distribution channels nationwide. Northland also co-packs other branded juice products and markets to various industrial customers who manufacture juice products. Northland believes it has been proactive in ensuring our products are safe and secure. We believe that food chain security is only as strong in its weakest link. We also believe in a level playing field for security because issues at other segments of the beverage industry directly affect Northland. Northland purchases both domestic and foreign juice concentrates, from all continents. Our questions and comments are listed by section.

How to register 1.231: Northland questions whether there will be a contingency plan if the web based system is not as efficient or more facilities register than expected. The notice indicates the paper backup system may not be able to process all non-Internet registrations in the initial 60 day window. It also appears better to register a facility that ultimately may not need to be registered (such as an unused food warehouse or on-farm fruit cleaning station) than to not register. Northland, for example, has two main processing facilities, but will probably register at least 9 locations. Will processors be

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considered to be producing adultered food if they have made good faith attempts to register but not been physically able to do so? Media reports on INS's new SEVIS web based foreign student tracking system indicate it is not as efficient as initially envisioned.

Trade names 1.232.d: This should be defined in 1.227. Does "trade name" mean "doing business as" or brand name? For contract manufacturers, brand names could run into the hundreds. It is not uncommon for brands packed to change on a weekly basis, requiring numerous registration updates. Is FDA suggesting that every trial run for a new brand requires an update? Does the regulation give a facility the legal authority to disclose trademarks or other confidential information without the consent of its owner? Northland suggests that "trade name" means "doing business as".

Updates 1.234.a: A 30 day update interval appears workable.

Updates 1.234.b: A business that ceases operations may not provide facility registration cancellation. FDA should consider other ways to purge obsolete registrations from its database.

In Section IV.D.b.iii of the economic analysis, FDA assumes that becoming aware of regulations is a normal business practice and therefore has no economic cost to either processors or trade associations. While it is true that a prudent business will learn of and follow all regulations affecting it, to state that this has no cost is simply not true. Northland estimates that the time to read the proposed regs, comment on them, implement the final regs internally, verify that our hundreds of trading partners are in compliance, and respond to hundreds of our customer's verification inquiries will take about 40 hours (40% manager/ 60% administrative) at a cost of at least $1500. Multiply this by the 400,000+ facilities FDA expects to register, and the cost becomes the most expensive part of registration. Being in the juice business, we have had recent experience in obtaining legally required HACCP plans from foreign juice processors, and know that this takes much more time than anticipated. Getting registration information from foreign warehouses and truckers will take even longer.

In Section IV.D.b.iii FDA estimates that it will take one hour to find and research the regulations with internet access. Northland believes this number is low. Since facility registrations are legal documents, businesses will spend more time researching the regs than FDA believes they will. Adequate research of the final regs will probably take 2 hours by each of two people (Technical and Legal), or 4 hours. This is 4 times FDA's estimate. As registration becomes routine in a few years, FDA's estimate will be fairly accurate, but the first year costs will be four times FDA estimates.

In Section IV.D.b.iii FDA's assumes 60 min to fill out and verify forms. This is correct if information can be copied from one form to the next.

In Section IV.D.b.iv FDA estimates that 20% of all facilities will need to update their registration each year. Based on normal turnover in personnel, business mergers and

acquisitions, changes in products manufactured and sold, and (4) depending on how "trade name" is defined, we estimate 50% updates per year may be necessary.

Northland intends to comply with these regulations fully, but several sections of the proposed regulations raise questions and could be revised to reduce the cost of compliance. Thank you for you consideration of our comments. Please feel free to contact me if you have any questions or we can provide additional information.

Sincerely,

Steve Cockram

Steve Cockram
Director of Technical Services
Northland Cranberries, Inc.

cc: Ricke Kress
Ken Iwinski